

WE CLAIM AS OUR INVENTION:

1. A system for implanting a bypass graft, including:
- a tissue dilating member having at its distal end a tissue dilating tip that converges in a distal direction;
 - a tissue puncturing tool supported within the dilating member and extending in the distal direction from the dilating tip, said tool adapted to puncture a tissue wall to form an orifice/enlargeable by the dilating tip; and
 - a graft comprising a substantially fluid impervious graft wall with first, second and third spaced apart regions of the wall having respective first, second and third openings formed through the graft wall;
- wherein the graft is adapted to be removably mounted on the dilating member in which the dilating member extends through the first and third openings, with the first opening disposed near the dilating tip and the third opening disposed proximally of the first opening so to enable use of the dilating member to insert the first region of the graft wall into a first orifice in the tissue wall for fixation of the first region therein; and
- wherein the graft further is slideable relative to the dilating member to permit a proximal withdrawal of the dilating member from the first region after said fixation, and further to allow an insertion of the dilating member into the second opening for securing the second region of the graft wall within a second orifice in the tissue wall whereby the graft provides a fluid flow conduit between the first orifice and the second orifice; and
- a closure mechanism for closing the third opening, following withdrawal of the dilating member from the graft.

2. The system of claim 1 further including first and second fixation

to near the first and second ends, respectively.

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FOOTNOTES

3. The system of claim 2 wherein the fixation elements incorporate features for mechanically securing the graft ends.

4. The system of claim 2 wherein at least one of the fixation elements comprises an electrically conductive heating element.

5. The system of claim 2 further comprising an expandable balloon mounted to the dilating member.

6. The system of claim 1 wherein said closure mechanism comprises a string or thread element disposed through the graft material around the third opening.

7. The system of claim 1 wherein said tissue puncturing tool comprises an elongate needle mounted slideably within the dilating member.

8. A system for deploying a bypass graft, comprising:

an elongate and flexible carrier having a proximal end and a distal end, insertable by the distal end for intraluminal movement toward a selected site along a body lumen while the proximal end remains outside of the body;

a tissue perforating mechanism proximate the distal end, positionable at a first location near the selected site and operable from the proximal end of the carrier to form a first opening through tissue at the first location, and further positionable at a second location near the selected site and operable to form a second opening through tissue at the second location;

a graft guide supported by the carrier and disposed near said distal end and movable into a guiding position in which the graft guide extends from the first location through the first opening to the second location and through the second opening;

a tubular graft adapted to be mounted to the carrier for movement along the carrier; and

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a graft controller operable to move the graft, when so mounted, distally along the carrier toward the graft guide and distally along the graft guide when the guide is in the guiding position to a bypass location in which the graft extends from the first location to the second location and further extends through the first and second openings.

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9. The system of claim 8 wherein the carrier comprises a catheter having a catheter lumen formed therethrough.

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10. The system of claim 9 wherein the graft guide comprises a dilator slideably contained in the catheter lumen and having a tapered distal tip, and wherein the tissue perforating mechanism comprises said tip and an elongate needle slideably contained within the dilator.

Sub D²

11. The system of claim 10 wherein the catheter lumen and the dilator are formed with substantially matching non-circular profiles to enable a transfer of torque from the catheter to the dilator.

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12. The system of claim 10 wherein the dilator is pre-shaped in a distal region, including the distal tip, to facilitate selective positioning of the tip by rotating the dilator.

13. The system of claim 10 further comprising a stop for limiting an extent of penetration of the needle into tissue.

14. The system of claim 10 wherein the controller comprises an elongate, tubular stylet insertable within the catheter lumen.

15. The system of claim 9 wherein the graft guide comprises a distal end region of the catheter and the tissue perforating mechanism comprises (i) a dilator

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having a tapered distal tip, said dilator contained slideably within the catheter lumen, and (ii) an elongate needle contained slideably within the dilator.

SubD2
16. The system of claim 15 wherein the controller comprises a stylet insertable into the catheter lumen.

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17. The system of claim 9 further comprising a fixation element to secure the graft at least at the second location.

SubD2
18. The system of claim 9 further comprising an inflatable balloon mounted to the graft guide near a distal end of the graft guide.

19. The system of claim 9 wherein the controller further is adapted to maintain the graft in the bypass location while the graft guide and the carrier are withdrawn proximally from the selected site.

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20. A process for transluminally deploying a bypass graft, comprising:
advancing an elongate catheter intraluminally toward a selected site along a body lumen;
with a distal end of the catheter near the selected site, forming a first opening through a tissue wall defining the body lumen via a tissue perforating mechanism mounted near a distal end of the catheter;
advancing the tissue perforating mechanism through the first opening to a location spaced apart from the first opening, then using the mechanism to form a second opening through tissue at said location;
advancing a graft guide distally through the first opening to said location and then through the second opening;
with the graft guide so positioned, advancing a tubular graft along the guide via a graft controller to a bypass location in which the graft extends from the first opening to the second opening and through the first and

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second openings, forming a bypass conduit in fluid communication with the body lumen; and
while maintaining the graft in said bypass position, proximally withdrawing the catheter, the tissue perforation mechanism and the graft guide.

21. The process of claim 20 wherein the graft guide comprises a tissue dilator slideably mounted within the catheter, and the step of advancing the graft guide comprises distally advancing the dilator relative to the catheter.

Sub D7
22. The process of claim 20 wherein said graft guide comprises a distal region of the catheter, and the step of advancing the graft guide comprises distally advancing the catheter until the distal region of the catheter extends through the first and second openings.

23. The process of claim 20 further comprising the step of securing the graft at proximal and distal end portions thereof to tissue at the first and second openings, respectively, with the graft at the bypass location.

24. The process of claim 23 wherein at least one of the first and second openings is formed through tissue of an organ defining a cavity, and whereby the graft, when secured, is open to the cavity.

25. The process of claim 23 wherein said first and second openings are formed through tissue walls of different blood vessels, and whereby the graft, when secured, provides a conduit fluid coupling the two different vessels.

26. The process of claim 20 wherein at least one of the openings is through an organ to a cavity of the organ.

27. The process of claim 20 wherein the first and second openings are formed through tissue walls of two different blood vessels.

28. An anastomotic connector comprising:
a collet having a tubular portion with a proximal end and a distal end, and
at least one radially self-expanding collet member disposed on the tubular
portion distal end.
29. The connector of claim 28 additionally comprising a tubular graft
joined to the collet.
30. The connector of claim 29 wherein the graft is laminated to the collet.
31. The connector of claim 29 wherein the graft is bonded to the collet.
32. The connector of claim 29 wherein the graft is joined to the collet over
an outer surface of the tubular portion proximal end to secure a vessel or organ wall
between the graft and the collet.
33. The connector of claim 28 wherein the collet comprises a memory
elastic material.
34. The connector of claim 28 wherein the collet comprises a material
selected from the group of stainless steel, nickel titanium, or thermoset plastic.
35. The connector of claim 28 wherein the self-expanding collet member
comprises a memory elastic material.
36. The connector of claim 28 wherein the self-expanding collet member
comprises a material selected from the group of stainless steel, nickel titanium, or
thermoset plastic.

37. The connector of claim 28 wherein the collet is capable of expanding into an expanded profile from a collapsed first profile.

38. The connector of claim 28 wherein the self-expanding collet member is configured to self-expand from a first confined position substantially colinear to the tubular portion to a second unconfined position extending radially outward upon release from the first confined position.

39. The connector of claim 38 wherein the self-expanding collet member forms an angle with the tubular portion of between about 45 degrees and 120 degrees when in the second unconfined position.

40. The connector of claim 39 wherein the angle is about 90 degrees.

41. The connector of claim 28 wherein the self-expanding collet member is adapted to attach a graft to a vessel or organ wall interior by direct contact between the self-expanding collet member and the vessel or organ wall interior without penetrating the vessel or organ wall interior.

42. An anastomotic connector comprising:
at least one encircling member having a distal end attachable to the graft, a proximal end attachable to the graft and configured to expand into and contact the interior of a vessel or organ wall.

43. The connector of claim 42 wherein the at least one encircling member is configured to bow outward to exert force against a vessel or organ wall and support a graft within a lumen defined by the vessel or organ wall.

44. The connector of claim 28 additionally comprising a membrane disposed about at least a portion of the collet member.

45. The connector of claim 44 wherein the membrane is at least partially impervious to fluid flow therethrough.

46. The connector of claim 28 additionally comprising a membrane forming a substantially fluid-impervious layer disposed about at least a portion of the collet member such that when said connector is deployed at a vessel puncture site, said membrane substantially prevents fluid flow through the puncture site.

47. The connector of claim 46 wherein the covering forms a continuous, annular, fluid-impervious layer.

48. A system for deploying and securing at least one end of a bypass graft to a vessel or organ, comprising:

a tissue perforator;

a tissue dilator;

a tubular carrier adapted for insertion into a vessel lumen, over the dilator and through an opening in the vessel lumen;

a connector attached to one end of a bypass graft adapted to compress into a reduced outer diameter in response to an external force and adapted to expand into an expanded outer diameter upon removal of the external force.

49. The system of claim 48 wherein the connector is self-expanding.

50. The system of claim 48 further comprising a stylet for advancing the connector and bypass graft through the carrier.

51. The system of claim 48 further comprising a compression fitting adapted to compress the vessel wall against the connector.

52. The system of claim 48 wherein the connector comprises at least one radially extending segment adapted to compress for insertion through the carrier and to expand to at least one resting geometry upon advancing beyond the distal end of the carrier.

53. A system for securing a bypass graft to at least one vessel comprising:

a tubular member having a first end, a second end, and a passageway defining an inner lumen extending between those ends;

a first connector attached to the first end of the tubular member;

a second connector attached to the second end of the tubular member;

a delivery mechanism adapted for producing a first opening at a first vessel wall location and a second opening at a second vessel wall location, expanding said first opening and said second opening, and maintaining said first opening and said second opening in an expanded orientation;

wherein the first connector and tubular member are adapted to be inserted as a single unit through the first opening; and

wherein the first connector and second connector are configured to secure the tubular member to the first and second vessel wall locations, respectively.

54. The system of claim 53 wherein at least one of the first and second connectors is self-expanding.

55. The system of claim 53 wherein the delivery mechanism is removable from at least one of the first vessel opening and the second vessel opening.

56. The system of claim 53 wherein at least one of the first connector and the second connector comprises at least one radially extending segment adapted to compress for insertion through the delivery mechanism and self-expand to a preshaped geometry upon advancing beyond the distal end of the delivery mechanism.

57. The system of claim 53 wherein at least one of the first connector and the second connector comprises at least one substantially annular member adapted to compress for insertion through the delivery mechanism and expand into contact with at least a portion of the vessel upon advancing beyond and end of the delivery mechanism.

58. The system of claim 57 wherein the at least one substantially annular member contacts and supports the vessel at a location other than one of the first opening or the second opening.

59. The system of claim 53 wherein the delivery mechanism comprises a needle and a dilator.

60. The system of claim 59 wherein the delivery mechanism additionally comprises a guiding catheter.

61. The system of claim 60 wherein the delivery mechanism additionally comprises a guidewire.

62. The system of claim 61 further comprising a stylet adapted to advance one or both of said first and second connectors and said tubular member through one or both of said first opening or second opening, respectively.

63. The system of claim 53 wherein the tubular member is a saphenous vein.

64. A method for creating an anastomosis between a tubular member and a mammalian vessel or organ segment, comprising:
positioning an end of the tubular member having a self-expanding connector attached thereto near the mammalian vessel or organ segment;

penetrating a wall of the vessel or organ segment to create an opening in said wall;

expanding the opening and advancing a distal portion of the connector through said opening such that the distal portion enters an interior of said vessel or organ segment and self-expands into an expanded configuration and the distal portion directly contacts an inner surface of the vessel or organ segment wall without further penetrating the wall.

65. The method of claim 64 wherein the tubular member and connector are positioned through the distal end of a catheter.

66. The method of claim 64 wherein the connector is not affixed to the tubular member but wherein the tubular member is advanced over and affixed to the connector after the connector is affixed in the vessel or organ segment.

67. The connector of claim 28 wherein said collet members comprise segments extending from said tubular collet portion.